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(54) PROSTHETIC VASCULAR GRAFT

(71) I, DAVID GOLDFARB, of 5706 E. Horseshoe Road, Paradise Valley, Arizona 85253, United States of America, a citizen of the U.S.A., do hereby declare the invention, for which I pray that a patent may be granted to us, and the method by which it is to be performed, to be particularly described in and by the following statement: —

The present invention relates to prosthetic vascular structures and, more particularly, to vascular protheses fabricated from highly expanded polytetrafluoroethylene.

Frequently in cardiovascular surgery, it is necessary to bypass or replace blood vessels, whether veins or arteries, to ensure an adequate and balanced blood flow to particular organs, extremities or areas of the body.

Unsuccessful attempts were made during the early years of this century to implant prosthetic or artificial vessels fabricated from glass and metal. With the availability of inert synthetic materials such as nylon, Orlon, Dacron and Teflon (polytetrafluoroethylene or PTFE) during the late 1940's and early 1950's, large arterial replacements were achieved with increasing degrees of success. (Orlon, Dacron and Teflon are Registered Trade Marks.)

Cardiovascular surgeons presently have available knitted and woven vessels of Dacron and Teflon which may be used as replacements for arteries having relatively large inside diameters (approximately 7 millimeters). However, no clinically acceptable small arterial prosthesis has been available; and surgeons have found it necessary to scavenge marginally important or superficial vessels, such as the saphenous vein, to serve as replacements for defective small bore arteries.

It is a principal object of the present invention to provide a prosthetic vascular structure capable of replacing or bypassing natural blood vessels having relatively small inside diameters as well as those vessels of intermediate and large bore.

The transplantation of saphenous veins from the patient's legs to more critical portions of the cardiovascular system entails numerous disadvantages: the entire surgical procedure is unduly protracted by having to first excise the venous replacement from one part of the patient's body, then prepare the replacement for implantation, and finally implant the substitute vessel at another point in the patient's cardiovascular system. Prolonged exposure to anesthesia and multiple incisions combine to increase the probability of both infection and post-operative discomfort.

Cardiovascular surgery frequently requires grafts of various lengths and diameters in achieving, for example: the femoral artery to popliteal artery bypass, the coronary artery bypass, the renal artery bypass, etc. Occasionally, however, especially in older patients, the saphenous veins themselves are inadequate for use as replacements; and in some instances only unacceptably short segments of the saphenous veins are available for transplantation.

tI is another object of the present invention to provide an artificial vascular structure which may be prefabricated in various lengths and diameters, thereby eliminating unnecessary incisions, minimizing exposure to anesthesia, conserving already limited surgical resources, and ensuring an ample supply of small bore vascular replacements.

Operations such as the femoral/popliteal bypass require especially long grafts which ideally taper in cross-sectional area from their proximal to their distal ends. Heretofore, transplanted saphenous veins have been used to accomplish this bypass procedure. Bcause blood flow through the saphenous vein is unidirectional in character, it is necessary to reverse the vein when it is being used as an arterial substitute. The inside diameter of a saphenous vein naturally tapers between its proximal and distal ends. Reversing the vein for implantation between the femoral and popliteal arteries results in a corresponding reversal of this taper so that the smaller diameter end must be grafted to the relatively large femoral artery while the

larger diameter end is grafted to the relatively small popliteal artery. The reversed taper of an implanted saphenous vein causes deceleration of the blood flow while the turbulence inducing discontinuities at the bypass junctions contribute to stasis and associated thrombosis.

It is a further object to provide a small bore prosthetic vascular structure which may be fabricated in relatively long segments, which segments decrease in inside diameter between proximal and distal ends so as to facilitate their implantation as peripheral artery replacements and ensure a close haemodynamic simulation of the corresponding natural vessel.

The inner surface of natural blood vessels is characterized by a thin, delicate layer of endothelial cells known as the intima. The primary function of this layer is to provide a smooth interface between the blood stream and the vessel wall. For example, a ruptured artery may, after healing, include rough or irregular protrusions from the wall into the blood stream. As the natural intima reestablishes itself over the wound area, it serves to lessen the severity in irregular wall transitions and thereby ensure laminar blood flow.

While the outer surface of a vessel prosthesis is encapsulated by fibrous growth as a result of normal rejection processes, the inner surface typically becomes isolated from the blood stream by a layer which has been referred to, with varying degrees of accuracy, as the neointima or pseudointima. To be classified as a true neointima, it would be necessary for the inner surface of the artificial vessel to be covered with an extremely thin lining of viable endothelial cells. Although such a lining would vary in thickness from point to point, it would be typically less than ten cells thick. There has heretofore existed no known vessel prosthesis of any size or configuration which, when implanted, would support the growth and maintenance of a true neointima layer. Accordingly, the vessel/blood interface associated with state of the art prostheses is characterized by a pseudointima consisting at best of a few irregularly distributed islands of endothelial growth but made up largely of compacted fibrin which has been flow sculptured by the blood stream. Occasionally, portions of this pseudointima will fracture or particulate and introduce emboli into the patient's blood stream.

The formation and maintenance of a true neointima requires a continuous extravascular source of nourishment to supplement whatever nourishment might be supplied by diffusion from the adjacent blood stream. In extremely short grafts (less than 2 to 3 centimeters), cellular ingrowth has been observed along the inside surfaces from the suture lines at the ends of the graft. In such cases, the tissue growth, augmented by capillary ingrowth, can provide a continuous nutrition route capable of supporting a viable neointima. However, the thickness of this inner layer of tissue is so great as to virtually occlude all but large bore grafts. Not only is ingrowth of this type unpredictable but it can be expected or tolerated at all only in very short grafts of relatively large inside diameter.

Extensive efforts have been made toward the fabrication of a porous vascular structure which would permit uniform transmural tissue ingrowth sufficient to ensure the formation and continuous nutrition of a true neointima layer. The culmination of this prior art effort is represented by grafts which are machine woven from threads consisting of tightly twisted Dacron or Teflon fibers. The threads used in the manufacture of these woven grafts while extremely small by garment industry standards, are enormous when viewed in the context of a haemodynamic system under pressure. As is true of any knitted or woven fabric, the minimum size of the interstices between threads is undermined by the diameter of the threads themselves. Because these interstices or voids are quite large in woven grafts, it is necessary to preclot the fraft by dipping it in blood in order to prevent excessive transmural leakage after implantation.

The large size of the threads used in prior art woven grafts and the tightness with which the constituent fibers are twisted renders each individual thread virtually impenetrable to cellular ingrowth and virtually beyond cellular circummigration. From the viewpoint of a single fibroblast, a knitted vessel prosthesis looks like two or three mammoth structures separated by equally mammoth voids which have been filled by the clotting process with masses of coagulated fibrin and proteinaceous matter. Viewed on a similar microscopic basis, the inner wall of the knitted graft appears as a series of large, rough cylinders of inert material separated by cavities which are equal or larger in breadth and depth to the diameter of the cylinders. As the blood flows through a prosthetic vessel of this type, the cavities are filled with slow moving blood while the irregularity and protrusion of the threads promotes turbulent blood flow. Thrombosis throughout the wall of the graft and at its inner surface, combined with the large size and separation of the knitted threads, serves to initiate build up of an irregular pseudointima layer while at the same time blocking and inhibiting transmural cellular ingrowth of the type necessary for the support of a uniform, viable neointima.

Accordingly, it is a major object of the

present invention to provide a porous vascular prosthesis characterized by small nodes interconnected by extremely fine fibrils to form an open structure which will allow uniform, controlled transmural cellular ingrowth and thereby ensure the establishment and maintenance of a thin, viable neointima as well as firm structural integration of the prosthesis into the body.

It is another object of the present invention to provide a vascular prosthesis characterized by a structure which is substantially impermeable to the flow of blood at normal pressures.

According to the invention, there is provided a prosthetic vascular structure of porous polytetrafluoroethylene having a macroscopically tubular configuration and a microscopic structure of irregularly shaped nodes connected to each other by fibrils; said vascular structure having:

a. a wall thickness from 0.2 to 0.8 millimeters;

b. a substantially uniform distribution of nodes throughout the tubular configuration;

c. an average density from 0.2 to 0.5 grams per milliliter; and

d. an average distance between nodes of from 6 to 80 microns;

whereby means are provided for smoothly conveying the flow of blood between at least two points in a living organism while ensuring and controlling cellular ingrowth through the wall of the tubular configuration to promote and nourish a thin, visible neointima over the inner surface thereof and to firmly attach the prosthetic vascular structure to adjacent tissue of the living organism.

The prosthetic vascular structure preferably has an average inside diameter of less than 8 millimetres, more preferably of from 2 to 6 millimetres.

In the accompanying drawings:

Figure 1 is a photomicrograph, taken at 250×, of a section through the wall of a vascular graft according to the present invention after having been implanted as a femoral artery segment for a period of eight months.

Figure 2 is a photomicrograph, taken by means of a scanning electron microscope at 1000×, showing the node and fibril structure characterizing highly expanded polytetrafluoroethylene vessel prostheses according to the present invention.

Figure 3 is a macroscropic view of a graft segment showing the sectional plane viewed in Figure 1.

Referring to Figure 1, it is seen that the graft of the present invention consists of a wall 1 having an outer surface 2 and an inner surface 3. Corresponding numerical denominations have been applied to the macroscopic view of the graft shown in Figure 3 where the cutaway section shows the plane of wall 1 depicted in the photomicrograph of Figure 1.

The graft as shown generally in Figure 3 comprises a proximal end 4 and a distal end 5. By convection blood flow through the graft is in the direction indicated by arrow 6, i.e., from the proximal end 4 to the distal end 5.

As can be seen in Figure 1, the inner surface 3 of graft wall 1 is covered by a uniform layer of endothelial cells forming the neointima 7. The outer surface 2 is covered by a uniform, firmly attached, encapsulation 8 of collagenous matter which includes substantial capillary ingrowth (not shown).

The graft wall 1 is a structure made up of polytetrafluorethylene nodes 9 which appear in Figure 1 as islands of inert white material. The polytetrafluoroethylene nodes 9 are interconnected by fine fibrils which, because of their extremely small diameters and their disaffinity for photographic strain, are not visible in Figure 1.

Figure 2 depicts the node/fibril structure of Figure 1 prior to implantation. The polytetrafluoroethylene nodes 9 and the many interconnecting fibrils 10 may be clearly observed in the absence of cellular ingrowth and at a magnification of approximately 4 times greater than Figure 1. On the other hand, the implanted graft of Figure 1 has been thoroughly and uniformly permeated by fibroblasts having cellular nuclei which appear in the photomicrograph as black dots 11. The nuclei of the endothelial cells forming the neointima 7 appear as block dots 11*a* in Figure 1. As may be observed, the neonitima is approximately eight cells in thickness.

Methods and techniques for expanding polytetrafluoroethylene have been known for many years. Partially expanded polytetrafluoroethylene has been used to provide electrical insulation on cables and to form low friction structural members such as bearings and piston rings, to provide sealing in liquid systems, and, without cylindrically acceptable or reproducible success, for artificial vessel replacements. See for example Soyer, et al, "A New Venous Prosthesis", *Surgery*, Vol. 72, page 864 (December 1972); and Matsumoto, et al, "A New Vascular Prosthesis for Small Caliber Artery", *Surgery*, Vol. 74, page 519 (October 1973).

The basic process for expanding polytetrafluoroethylene is quite simple: The constituent resin is first subjected to shear by, for example, extrusion into the desired geometrical configuration. The extrudate is then heated at a temperature below the sintering temperature of 327°C and physically stretched or expanded along at least one axis. The expanded member is then physically restrained against contraction and is

sintered by brief exposure to temperatures in excess of 327°C, thereby crystallizing the expanded structure and providing moderate tensile strength of up to 6500 psi. As the raw extrudate is stretched, the non-porous polytetrafluoroethylene separates into solid nodes 9 of polytetrafluoroethylene which remain structurally interconnected by polytetrafluoroethylene fibrils 10 which are drawn from the nodes during expansion. See Figure 2. Node size and distribution in the final product is adversely affected by: very rapid expansion, uneven expansion, insufficient heating, non-uniform heating, and irregularly distributed expansion forces. The distance between nodes 9 is directly proportional to the extent to which the extrudate has been expanded. When polytetrafluoroethylene is properly expanded along one axis, virtually no dimensional changes are observed in the orthogonal direction. The directional vector 12 in Figures 1, 2 and 3, indicates the axis along which grafts embodying the present invention are typically expanded.

As can be seen in Figures 1 and 2, the nodes 9 are very generally ellipsoidal in configuration with their major axis disposed at approximately right angles to the axis of expansion 12 and in a generally radial orientation with respect to the tubular configuration of the graft. The nodes 9 are of generally uniform size and are distributed in a homogeneous pattern throughout the wall 1. Furthermore the nodes are extremely small, typically less than a few times the size of a normal fibroblast or red cell, i.e. less than about 18 microns.

Because the minor axes of the ellipsoidal nodes 9 are transverse to the generally radial direction typifying cellular ingrowth, the invading fibroblasts never encounter any massive polytetrafluoroethylene barrier. It is believed that the size and orientation of the nodes 9, together with their tapered configuration, facilitates cellular migration and ingrowth. To avoid substantial impediment to ingrowth, the average minor axis dimension of each node 9 is less than three times the major dimension of a typical red cell, i.e., less than about 18 microns.

It has been found that the average internodular distance, as measured along the axis of expansion 12, must fall within a relatively narrow range of values, viz., between 6 and 80 microns. As will be appreciated by those skilled in the art, the term "average" when used in conjunction with internodular distance and node size cannot be used or interpreted with statistical precision; rather, the term is intended to connote a nominal or typical dimension derived from a broad sample. By way of example, where the average internodular distance is said to be 30 microns, it would be expected that some of the nodes would be separated by only a few microns while others might be separated by 90 or 100 microns. In the ideal graft, each node 9 would have a perfect ellipsoidal shape and would be separated from its neighbours by uniformly distributed fibrils 10 of equal lengths. Unfortunately, such perfection is rarely, if ever, achieved in a microscopic environment.

Where the average internodular distance is less than the major dimension of a typical red cell, or approximately 6 microns, inadequate cellular ingrowth has been observed. In such cases, the node/fibril structure is so tightly packed as to preclude either the establishment or continued nutrition of a viable neointima.

Associated with very large internodular distances is a loss of tensile strength and overall structural integrity. The graft becomes progressively more pliable and progressively more difficult to handle during surgery. Excessively expanded grafts will be subject to deformation and leakage at the suture line. Furthermore, excessive cellular ingrowth has been observed in grafts having an average internodal distance in excess of 80 microns. Where the inside diameter of the graft is critically small, excessive cellular penetration of this type can lead to the formation of a speudointima or an unacceptable thickening of the neointima with an accompanying occlusion of the lumen.

As the average internodular distance is extended beyond, for example, 150 to 200 microns, the graft structure becomes progressively more permeable to blood flow and is characterized by substantial interstitial clotting and progressively decreasing and non-uniform cellular ingrowth. Ultimately, were it possible to reproduce internodular distances comparable in size to the interstitial voids of the size characterizing woven grafts, then virtually all transmural growth would be inhibited, and the support of a true neointima would be impossible.

Just as the nodes 9 must be of such size, configuration and orientation to avoid substantial impediment to cellular ingrowth, so too, they must be substantially uniformly distributed throughout the length and cross-section of the graft. It has been found that clumps or groupings of closely packed nodes can serve as barriers to ingrowth. It has also been found particularly critical to the creation and support of a viable neointima, that the nodes immediately adjacent to and defining the inner surface 3 of the graft be uniformly distributed, i.e., neither clumped so as to block the flow of nutrition to the neointima nor so widely spaced as to define deep thrombosis inducing irregularities in the inner surface 3.

A phenomenon referred to as "skin effect" is attributed to non-uniform force distribution occurring either during the extrusion or

the expansion of tubular structures of the type embodying the present invention. Skin effect involves a relatively high concentration of nodes in a given circumferential plane, usually either the inner surface 3 or the outer surface 2. A slight skin effect is observed on the outer surface 2 of the graft segment shown in Figure 1, while the inner surface 3 is characterized by an open regular node pattern. The limited skin effect observed at outer surface 2 is obviously acceptable in degree since, as Figure 1 clearly shows, it has not adversely affected cellular ingrowth.

In some instances, skin effect is a highly localized phenomenon, yet in other instances it may be observed over the entire inner or outer surface of the graft. A skin effect which might be acceptable at the outer surface of the graft might well be unacceptable at the inner surface because of the greater criticality for establishing a regular structure which will allow ample and uniform nutrient flow to, and mechanical support for, the neointima 7.

Wall thickness is another factor affecting the establishment and maintenance of a viable neointima in grafts embodying the present invention. For any particular internodular distance within the acceptable range, the thickness of the graft wall can be made so great as to preclude complete transmural cellular migration and ingrowth.

Nutrition of the fibroblasts in wall 1 as well as the endothelial cells forming the neointima 7 depends primarily upon capillary ingrowth, which normally becomes well developed within the third and fourth weeks after implantation of the graft. Diffusion of nutrients from the bleed stream itself, especially during the period immediately following implantation, and transmural diffusion of nutrition also contribute to tissue growth.

There is a limit to which cellular ingrowth will penetrate from the outer surface 2 into a graft wall. The depth or extent of nutritional diffusion is also limited. Where the wall of a particular graft is too thick (considering the internodular distance), an unnourished calcifying layer will form within the wall of the graft in any area which is so far removed from the outer surface 2 as to be beyond the range of normal cellular ingrowth and which is too far from the inner surface 3 to receive nutrients by diffusion from the blood stream. This calcifying layer, itself a result of inadequate nutritional flow, acts as a barrier, further inribiting the growth of new cells. Within the acceptable range of average internodular distances, it has been found that wall thicknesses greater than 0.8 millimeters are excessive.

While excessive wall thickness may result in an unacceptable stiff graft or one which inhibits transmural ingrowth, insufficient wall thickness results in a limp, unmanageable graft or one which allows excessive cellular ingrowth. Thus, wall thickness and internodular distance are the two prime determinants of graft pliability and strength and are also the two major factors which combine two control the extent and uniformity of transmural ingrowth.

Grafts embodying the present invention, having wall thicknesses in the range between 0.2 and 0.8 millimeters and characterized by average internodular distances in the range between 6 and 80 microns have exhibited excellent mechanical properties and have resulted in controlled ingrowth sufficient to ensure the support of a thin, viable neointima which does not unduly restrict the lumen of the graft. Grafts falling outside these ranges have been found to be marginal or clinically unacceptable. Grafts falling into these preferred ranges are characterized by moderately high tensile strength in the range between 2500 and 6500 pounds per square inch and average density between 0.2 and 0.5 grams per milliliter.

In the introductory portion hereof it was pointed out that reversed saphenous vein grafts have been frequently used to bypass diseased segments of peripheral arteries. This requires anastomosis of the graft to arteries having substantially different diameters. The proximal artery always has a larger diameter than the distal artery, as is true, for example, in the case of the common femoral artery-to-popliteal artery bypasses performed for the purpose of routing blood flow around obstruction in the superficial femoral artery. The femoral artery normally has an internal diameter of 5 to 8 millimeters whereas the popliteal artery is typically between 2 and 6 millimters in internal diameter. If a constant diameter prosthesis or a reversed saphenous vein is used in accomplishing the bypass, a suddent cross-sectional area change is present at either or both ends of the graft. From a haemodynamic point of view, these sudden area changes are highly disadvantageous in that they tend to produce turbulence with pockets of stasis, causing deposition of platelets, fibrin and cellular materials and thus the formation of thrombi which can ultimately propagate to occlusion of the vessel. These problems are eliminated in accord with one embodiment of the present invention wherein the inside diameter of the prosthesis tapers gradually over its entire length from the diameter of the larger proximal vessel down to the diameter of the smaller distal vessel. Tapering of the graft promotes streamlining of the blood and ensures laminar rather than turbulent flow. Tapering also results in accelerated blood flow with an associated increase in the velocity of the blood elements;

as opposed to deceleration, which characterizes flow through the reversed saphenous vein. Thus, tapered grafts of the present invention not only provide for the growth and maintenance of a viable neointima but also promote accelerated laminar blood flow with the resultant elimination of clotting due to stasis and turbulence.

In addition to the significant biomedical, haemodynamic and mechanical advantages which accompany the use of vessel prostheses of the type described herein, numerous surgical, procedural and post-operative benefits are also realized. Cardiovascular surgery calling for a small bore vessel substitute has heretofore required initial harvesting of the saphenous vein for use as a graft. This involves the following surgical steps which are rendered unnecessary by the present invention:

1. groin incision and proximal dissection of the patient's saphenous vein;
2. lower thigh incision and distal dissection of the patient's saphenous vein;
3. multiple medial thigh incisions for completion of the saphenous vein dissection;
4. removal of the saphenous vein and careful ligation of all branches;
5. reversal of the saphenous vein prior to implantation so that venous valves do not obstruct arterial flow, thereby necessitating the awkward anastomosis of the small (appromately 3 millimeters) distal end of the vein to a substantially larger proximal artery and, in the case of a peripheral artery replacement, anastomosis of the relatively large proximal end of the vein to a very small bore distal artery;
6. careful inspection for possible leaks from the various branches in the graft or from those remaining in the patient's thigh; and,
7. closing of the multiple incisions necessitated by removal of the saphenous vein.

Use of expanded polytetrafluoroethylene grafts of the type described and claimed herein not only eliminates these unnecessary surgical procedures, but also shortens operative and anesthetic time by between one and two hours, does away with the post-operative discomfort and possible infection resulting from numerous leg wounds and greatly conserves already limited hospital and surgical resources.

The manufacture of prosthetic vascular structures embodying the present invention is extremely simple and can be readily performed with the most rudimental laboratory equipment, realizing of course that more sophisticated equipment is required for volume production and quality control. The basic physical, chemical and procedural parameters for expanding polytetrafluoroethylene are known; however, an example will be given illustrating the fundamental technique involved in making small bore polytetrafluoroethylene grafts having the claimed structure.

Polytetrafluoroethylene is extruded to form tubing having an average inside diameter of approximately 4 millimeters and an average wall thickness of approximately 0.5 millimeters. Unsintered tubing of this type, identified by the manufacturer's No. S16882—7, may be obtained from W. S. Shamban Company (71 Mitchel Road, Newberry Park, California 91320). The unsintered extrudate, which is quite fragile, is carefully cut with a razor blade into lengths of, for example, 7.3 centimeters. Small aluminum plugs of suitable configuration are inserted into each end of the tubing and secured thereto by tightly wrapped stainless steel wire. A relatively short end segment is thus confined between the inserted plugs. These plugs provide points for handling and attachment during the subsequent heating, elongation and sintering steps.

The tubing and plug assembly is placed in a uniformly heated oven for approximately one hour at 275°C. Thereafter, the assembly is removed from the oven, the plugs are grasped and stretched apart manually to obtain a tubular length of 23 centimeters. The time required for removal and elongation should be made as short as possible to reduce the effects of cooling. Elongation should be carried out at a moderate, uniform rate and the plugs should be moved apart along a common axis of expansion to ensure uniform force distribution. Typically, this manual operation has required less than ten seconds and has yielded good results.

The elongated assembly is then secured against contraction by restraining the plugs at the desired separation.

While still restrained, the elongated assembly is returned to the oven for approximately forty-five seconds at 400°C, during which time the node/fibril structure is sintered and becomes fixed. The elongated grafts are then cut to the desired lengths and after sterilization are ready for implantation.

In large commercial applications, expansion is achieved mechanically in the oven itself at closely controlled rates and is immediately followed by sintering. However, excellent grafts, such as the one shown in Figure 1, have been obtained by the simple laboratory techniques outlined above.

Fabrication of tapered grafts such as those used for peripheral artery replacement involves the additional step of reshaping a sintered tube of desired length and diameter over a tapered stainless steel mandrel which has been heated to approximately 300°C. After the entire assembly is allowed to cool, the slightly re-expanded graft retains the shape of the mandrel and may be removed for use without further heat treatment.

It will be apparent to those skilled in the art that the disclosed prosthetic vascular structure may be modified in numerous ways and may assume many embodiments and configurations other than those specifically set forth and described above. For example, the basic prosthetic structure may be made in various lengths and having average inside diameters of less than 40 millimeters without affecting the structural integrity or operativeness of the graft. Various secondary configurations such as bifurcated grafts may also be produced. Because grafts embodying the present invention are substantially impermeable to transmural blood flow, it will be obvious to those of ordinary skill in the art that the patients need not be heparinized to avoid leakage through the graft.

WHAT I CLAIM IS:—

1. A prosthetic vascular structure of porous polythetrafluoroethylene having a macroscopically tubular configuration and a microscopic structure of irregularly spaced nodes connected to each other by fibrils; said vascular structure having:

a. a wall thickness from 0.2 to 0.8 millimeters;

b. a substantially uniform distribution of nodes throughout the tubular configuration;

c. an average density from 0.2 to 0.5 grams per milliliter; and

d. an average distance between nodes of from 6 to 80 microns;

whereby means are provided for smoothly conveying the flow of blood between at least two points in a living organism while ensuring and controlling cellular ingrowth through the wall of the tubular configuration to promote and nourish a thin, viable neointima over the inner surface thereof and to firmly attach the prosthetic vascular structure to adjacent tissue of the living organism.

2. A prosthetic vascular structure as claimed in claim 1, wherein the nodes are generally ellipsoidal in shape and have an average dimension along their minor axes less than about 18 microns.

3. A prosthetic vascular structure as claimed in claim 2, wherein the major axes of the nodes are in a generally radial orientation with respect to the tubular configuration.

4. A prosthetic vascular structure as claimed in any preceding claim, having an average inside diameter of less than 40 millimetres.

5. A prosthetic vascular structure as claimed in claim 4, having an average inside diameter of less than 8 millimeters.

6. A prosthetic vascular structure as claimed in claim 5, having an average inside diameter of from 2 to 6 millimeters.

7. A prosthetic vascular structure as claimed in any preceding claim, having a tensile strength from 2500 to 6500 psi.

8. A prosthetic vascular structure as claimed in any of claims 1, 2, and 3, which tapers from a first inside diameter at one end to a second inside diameter at the other end.

9. A prosthetic vascular structure as claimed in claim 8, wherein the first inside diameter is from 5 to 8 millimeters and the second inside diameter is from 2 to 6 millimeters.

10. A prosthetic vascular structure, substantially as herein described, with reference to the accompanying drawings.

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2 SHEETS

COMPLETE SPECIFICATION

This drawing is a reproduction of the Original on a reduced scale

Sheet 1

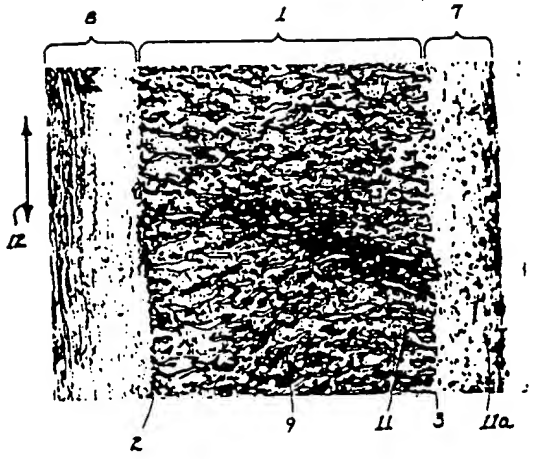

fig. 1

fig. 2

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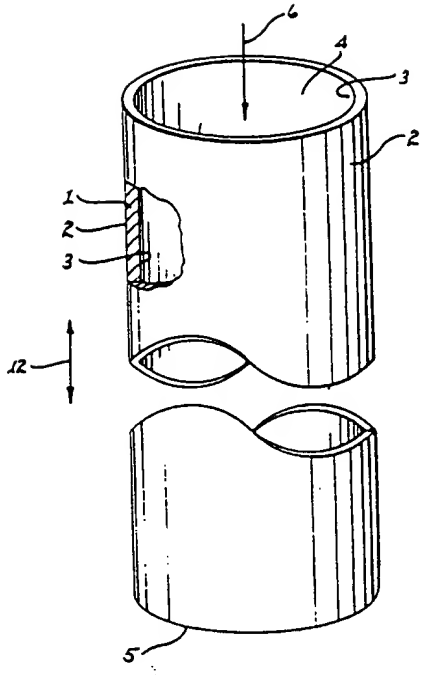

Fig. 3